

Notice of Allowability

Application No.

09/887,145

Examiner

Christopher Nichols, Ph.D.

Applicant(s)

KIM, SEUNG U.

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 19 September 2003.
2. ☒ The allowed claim(s) is/are 1, 4-11, and 15.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: _____.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No. _____.
 - (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
 - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892) | 2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 4 <input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____. |
| 5 <input type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. _____. | 6 <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 7 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9 <input type="checkbox"/> Other |

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. The Response filed 19 September 2003 has been received and entered in full.
2. Claims 1, 10, 13, 14, and 15 have been amended. Claims 18 and 19 have been added.

Withdrawn Objections And/Or Rejections

3. The Objection to the Drawings as set forth at pp. 2 ¶2-3 in the previous Office Action (22 May 2003) is *withdrawn* in view of Applicant's citation of the relevant reference signs in the instant Specification (19 September 2003).
4. The instant Application is now in compliance with Sequence Rules as set forth at pp. 2-3 ¶4 in the previous Office Action (22 May 2003).
5. The Objection to claims 12, 13, and 14 as set forth at pp. 3 ¶5 in the previous Office Action (22 May 2003) is *moot* in view of Applicant's acceptance of the Examiner's Amendment listed herein canceling said claims.
6. The Rejection of claims 1-17 as set forth at pp. 3-4 ¶6-9 in the previous Office Action (22 May 2003) is *withdrawn* in view of the abandonment of Application 09/855468 (3 April 2003).
7. The Rejections of claims is withdrawn in view of Applicant's acceptance of the Examiner's Amendment listed herein. It is acknowledged that Applicant accepted said Examiner's Amendment for the purpose of expedited prosecution without forfeiting the right to pursue additional subject matter in later applications.

EXAMINER'S AMENDMENT

Art Unit: 1647

8. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

In the claims:

Claim 1 (Currently Amended) A genetically modified human microglia cell which can be maintained as a stable, substantially homogeneous cell line in vitro, said genetically modified cell comprising: a microglia cell of human origin which is stable when maintained in culture and which

(i) has demonstrable phagocytic properties;

(ii) produces substantially homogenous progeny continuously while maintained in culture;

(iii) presents at least CD11b and CD68 as surface antigens; and

(iv) contains human genomic DNA which has been genetically modified to include a viral vector carrying at least one DNA segment encoding an exogenous gene for intracellular expression wherein said viral vector is an amphotrophic retroviral viral vector and wherein said viral vector includes as exogenous DNA sequence encoding a v-myc gene.

Claims 2-3 (Cancelled)

Art Unit: 1647

Claim 4 (Currently Amended) The genetically modified human microglia cell as recited in claim 1 further comprising the presence of the surface antigen RcA-lectin₃.

Claim 5 (Original) The genetically modified human microglia cell as recited in claim 1 further comprising the presence of P_{2Y1} receptors.

Claim 6 (Currently Amended) The genetically modified human microglia cell as recited in claim 1 further comprising the presence of the surface antigens HLA-ABC (MHC class I)₃ and HLA-DR (MHC class II).

Claim 7 (Original) The genetically modified human microglia cell as recited in claim 1 wherein said cell expresses at least one active substance selected from the group consisting of cytokines and chemokines.

Claim 8 (Currently Amended) The genetically modified human microglia cell as recited in claim 6 7 wherein said expressed active substance is selected from the group consisting of M1P-1 β , MCP-1, IL-1 β , IL-6, IL-8, IL-12, and IL- 15.

Claim 9 (Original) The genetically modified human microglia cell as recited in claim 1 wherein said cell is in a non-stimulated state.

Art Unit: 1647

Claim 10 (Original) The genetically modified human microglia cell as recited in claim 1 wherein said cell is in a stimulated state.

Claim 11 (Currently Amended) The genetically modified human microglia cell as recited in claim 10 wherein said stimulated cell overexpresses at least one pharmacologically active ~~composition~~ substance selected from the group consisting of cytokines and chemokines.

Claims 12-14 (Cancelled)

Claim 15 (Currently Amended) A method for transforming human microglial cells into a genetically modified microglial cell line of claim 1, said method comprising:

(a) obtaining human microglial cells;

(b) culturing said human microglial cells;

(c) transfecting said cultured human microglial cells using ~~a viral vector encoding at least an oncogene~~ an amphotrophic replication incompetent retroviral vector encoding a v-myc oncogene; and

(d) expanding said transfectants in culture media as an immortalized, substantially homogeneous cell line.

Claims 16-19 (Cancelled)

Art Unit: 1647

Authorization for this examiner's amendment was given in a telephone interview with David Prashker (Reg. No. 29,693) on 12 November 2003.

REASONS FOR ALLOWANCE

9. The following is an examiner's statement of reasons for allowance:
10. The Examiner's amendment clarified the issue at hand which was how a skilled artisan could make the genetically modified human microglial cell lines as originally claimed in claims 1-14. By amending claim 15 to be dependent upon claim 1, this obviated the rejection under 35 U.S.C. §112 ¶1 for lack of a deposit of biological material as sent forth in the previous Office Action (22 May 2003).
11. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Summary

12. Claims **1, 4-11, and 15** are hereby allowed.
13. The Examiner acknowledges that acceptance of the above Examiner's Amendment does not mitigate in any way, shape, or form, Applicant's right to pursue additional subject matter in continuation, continuation-in-part, and/or divisional applications pursuant to 35 U.S.C. §120 and §121.

Art Unit: 1647

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is 703-305-3955. The examiner can normally be reached on Monday through Friday, 8:00AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CJN
November 12, 2003


GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1647

Art Unit: 1647

8. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

In the claims:

Claim ~~X~~¹ (Currently Amended) A genetically modified human microglia cell which can be maintained as a stable, substantially homogeneous cell line in vitro, said genetically modified cell comprising: a microglia cell of human origin which is stable when maintained in culture and which

- (i) has demonstrable phagocytic properties;
- (ii) produces substantially homogenous progeny continuously while maintained in culture;
- (iii) presents at least CD11b and CD68 as surface antigens; and
- (iv) contains human genomic DNA which has been genetically modified to include a viral vector carrying at least one DNA segment encoding an exogenous gene for intracellular expression wherein said viral vector is an amphotrophic retroviral viral vector and wherein said viral vector includes as exogenous DNA sequence encoding a v-myc gene.

Claims 2-3 (Cancelled)

Art Unit: 1647

²
Claim ~~4~~ (Currently Amended) The genetically modified human microglia cell as recited in claim ~~1~~
~~1~~ further comprising the presence of the surface antigen RcA-lectin₅.

³
Claim ~~5~~ (Original) The genetically modified human microglia cell as recited in claim ~~1~~ further
comprising the presence of P_{2Y1} receptors.

⁴
Claim ~~6~~ (Currently Amended) The genetically modified human microglia cell as recited in claim ~~1~~
~~1~~ further comprising the presence of the surface antigens HLA-ABC (MHC class I); and HLA-
DR (MHC class II).

⁵
Claim ~~7~~ (Original) The genetically modified human microglia cell as recited in claim ~~1~~ wherein
said cell expresses at least one active substance selected from the group consisting of cytokines
and chemokines.

⁶
Claim ~~8~~ (Currently Amended) The genetically modified human microglia cell as recited in claim ~~6~~
~~6~~ wherein said expressed active substance is selected from the group consisting of M1P-1 β ,
MCP-1, IL-1 β , IL-6, IL-8, IL-12, and IL-15.

⁷
Claim ~~9~~ (Original) The genetically modified human microglia cell as recited in claim ~~1~~ wherein
said cell is in a non-stimulated state.

Art Unit: 1647

Claim ~~10~~⁸ (Original) The genetically modified human microglia cell as recited in claim ~~1~~¹ wherein said cell is in a stimulated state.

Claim ~~11~~⁹ (Currently Amended) The genetically modified human microglia cell as recited in claim ~~10~~⁸ wherein said stimulated cell overexpresses at least one pharmacologically active ~~composition~~ substance selected from the group consisting of cytokines and chemokines.

Claims 12-14 (Cancelled)

Claim ~~15~~¹⁰ (Currently Amended) A method for transforming human microglial cells into a genetically modified microglial cell line of claim ~~1~~¹, said method comprising:

- (a) obtaining human microglial cells;
- (b) culturing said human microglial cells;
- (c) transfecting said cultured human microglial cells using ~~a viral vector encoding at least an onco-gene~~ an amphotrophic replication incompetent retroviral vector encoding a v-myc oncogene; and
- (d) expanding said transfectants in culture media as an immortalized, substantially homogeneous cell line.

Claims 16-19 (Cancelled)
